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U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
Washington 25, D. C.

FOR RELEASE TO TRADE AND PROFESSIONAL JOURNALS
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The Food and Drug Administration of the Department of Health, Education, and Welfare reported today actions it has taken to put into effect the provisions of the new inspection amendment to the Federal Food, Drug, and Cosmetic Act.

Commissioner of Food and Drugs Charles W. Crawford said that FDA inspectors are now giving written notice of intention to inspect at the time when they present their credentials to the owner, operator, or agent in charge of the plant. Such notices give the date, time of day, name of the inspector and the address of the district office to which he is assigned, and the name and address of the plant.

Inspectors are also leaving written reports on conditions or practices which indicate that any products in the establishment contain filth or decomposition or have been prepared, packed or held under insanitary conditions. Inspectors leave these reports with the individual to whom they presented the notice of inspection, or if he is not available at the close of inspection, with another responsible official.

In compliance with other provisions of the new law, inspectors are now giving written receipts for all samples taken in connection with an inspection. District offices of the Food and Drug Administration will report promptly to the management of food plants the results of analyses of food samples taken in such plants for determining the presence of filth or decomposition.

In connection with these actions Commissioner Crawford said that while some phases of FDA inspections are now clearly on a mandatory basis, there are others which Congress apparently intended to be put on a voluntary basis.

In explanation he said:

"The law provides penalties for refusal to permit inspection of factories, warehouses, establishments or vehicles in which foods, drugs, cosmetics or devices are manufactured, processed, packed or held for introduction into interstate commerce, or held after such introduction, or in which they are transported, and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

"Modern production and distribution are carried on to a large extent through the medium of written instructions and records. The legislative history indicates Congress did not intend to include prescription files, formula files, complaint files, and personnel files within the scope of required inspections. FDA interprets this to mean that inspection of these records will be on a voluntary basis.

"Accordingly, inspectors have been instructed to ask permission to see such records or files whenever there is any need or reason to examine them or to obtain information contained in them.

"The inspector may state reasons for asking to examine a particular record or file but will not otherwise press the owner, operator or agent for permission to see it.

"The Food and Drug Administration will not attempt to predetermine what action may be appropriate in future situations which seem to necessitate inspection of records, but will endeavor to resolve these problems as they arise, keeping in mind the health, safety and interest of consumers and the Congressional intent in the statute as a whole to protect public health.

"In 47 years since passage of the original Pure Food and Drug Law the great majority of the regulated industries have always cooperated fully in

observing its provisions and by assisting in our work of enforcement. We have every reason to believe the regulated industries will continue this cooperation."

(A copy of Public Law 217 is enclosed. Also enclosed is a copy of Public Law 201 which adopts the name, chlortetracycline, for the antibiotic, "Aureomycin".)

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